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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,427	09/05/2003	Michael Kane	KAN1.001	7573

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ELMAN TECHNOLOGY LAW, P.C.
P. O. BOX 209
SWARTHMORE, PA 19081

EXAMINER	
VAKILI, ZOHREH	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,427	KANE, MICHAEL	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 are presented for examination.

Applicant's response to the restriction requirement filed on April 18, 2007 is acknowledged. Accordingly, Applicant traverses the restriction requirement to Groups I and II and withdraws the claims of Group III.

Applicant asserts that Group I and Group II should be rejoined and examined on their merits, since; the elements recited are the same in claims 1 and 3. Applicant arguments are persuasive and Groups I and II will be joined and examined on their merits.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "effective amount" is present. This phrase is vague and indefinite as to what "effective amount" means. It is unclear as to what the amount is effective to achieve. The last 2 lines of claim 1 recites resting of the skin whereas the first line of claim 1 recites reducing the appearance of facial wrinkles. Therefore, the effectiveness of the amount confusingly is not defined as to whether it is controlled by the amount to

reduce facial wrinkles or to rest the skin.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Donovan (PUB. NO. US2004/0009180 A1).

Donovan teaches a pharmaceutical composition for transdermal administration of neurotoxins, such as a botulinum toxin. The pharmaceutical compositions are topically applied on a patient (see abstract). A Botulinum toxin type A complex (BOTOX®) has been by the U.S. Food and Drug Administration for the treatment of blepharospasm, and treatment of glabellar wrinkles. Clinical effects of peripheral intramuscular

botulinum toxin type A are usually seen within a day or a few hours after injection. The typical duration of symptomatic relief from a single intramuscular injection of botulinum toxin type A averages about three to four months (see paragraph 9). A commercially available botulinum toxin containing pharmaceutical composition is sold under the trademark BOTOX® (available from Allergen, Inc., of Irvine, Calif.). BOTOX® consists of a purified botulinum toxin type A complex (see paragraph 0018). Transdermal administration of pharmaceuticals has been the subject of research in attempt to provide an alternative route of administration of medications without undesirable consequences associated with injections and oral delivery. Needles often cause localized pain. Oral administration suffers from poor bioavailability of medications. Transdermal administration techniques attempt to overcome these shortcomings (see paragraph 40). A patient with bow furrows requests botulinum toxin to reduce the wrinkles. A suspension of BOTOX® is topically applied to the patient's forehead. In about 2-3 days, the patient begins to notice that the forehead wrinkles are reduced in number. At about 7 days, the wrinkles are gone. The effects of the BOTOX® last for about 4 months (see paragraph 91).

Reducing the BOTOX® treatment to zero BOTOX® is clearly a decreased amount as required in the instant claims for subsequent treatment. The instant claims do not exclude zero as a decreased treatment amount.

Consequently, the reference anticipates the claimed invention defined in claims 1-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanin et al. (US Patent No. 7140371 B2).

Hanin et al. teach in the present invention is based upon the discovery that a skin surface topographical method can be used to determine an effect of a Clostridial toxin or Clostridial neurotoxin upon a muscle. For example, the effect determined through use of the disclosed method can be a paralytic effect (i.e. inability to contract), including onset of effect, peak effect and duration of paralytic effect of a Clostridial toxin upon a muscle. Or, the effect determined may be a reduction in one or more characteristics of a wrinkle or wrinkles (see col. 10, lines 55-65). The botulinum neurotoxin of the first composition is a botulinum toxin type A also known as BOTOX® (see col. 14, lines 58-62). In view of the disclosure herein, a method of comparing botulinum neurotoxins or comparing effects caused by botulinum neurotoxins may comprise measuring a skin wrinkle at a location or region of an individual or measuring

or otherwise quantifying one or more characteristics of such a skin wrinkle or skin wrinkles, administering a botulinum neurotoxin to a muscle in proximity to the skin wrinkle to reduce the wrinkle, and measuring the skin wrinkle at the location after administration of the botulinum neurotoxin. The method may be repeated for a second botulinum neurotoxin after the effects of the first botulinum neurotoxin have worn off (see col. 16, lines 8-23). After administration of the botulinum toxins, a second impression of the skin surface region is made while the first and second muscles are at a second maximum voluntary contraction. The first and second impressions are then examined and a skin wrinkle measurement is obtained (see col. 16, lines 38-42). The specific amount of a botulinum toxin administered depends upon a variety of factors to be weighed and considered within the discretion of the attending physician and in each of the examples insignificant amounts of botulinum toxin enter appear systemically with no significant side effects (see col. 17, lines 52-57). Dosages of the neurotoxin, such as botulinum toxin, in the compositions may vary. The compositions contain a therapeutically effective amount of neurotoxin, for example, between about I unit and about 500 units of botulinum toxin type A (see col. 17, lines 58-62). The patients' profiles and an administration schedule with a target end date is described in a clinical study for determining effect of a botulinum toxin upon a frontalis muscle (see col. 22, Example 4).

It would have been obvious to one skilled in the art to use the teachings of Hanin et al. to generate amethod for reducing facial wrinkles by administering a therapeutically effective amount of botulinum toxin A. Therefore, one having ordinary

skill in the art at the time of invention was made would have been motivated to use the teachings of the prior art cited above for a method of reducing facial wrinkles using botulinum toxin A as claimed in the present invention.

In the absence of any criticality/unexpected results presently claimed invention is considered *prima facie* obvious over the prior art for the reasons cited above.

Hanin et al. is supported by priority disclosures dating back to 3/14/2002.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614

October 10, 2007

Ardin H. Marschel 10/15/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER